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John C. McMahon				
PO Box 30069				
Kansas City, MO 64112				
EXAMINER				
WOO, JILLAN W				
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3773				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/767,646

Applicant(s)

JACKSON, ROGER P.

Examiner

Julian W. Woo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 March 2008.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 5-14 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-3 and 5-14 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claim 14 is rejected under 35 U.S.C. 102(b) as being anticipated by Dent (GB2140523). Dent discloses, at least in figures 9 and 14-16, a plug closure including a closure (14A) having at least a pair of bores (20) each positioned in spaced relationship to both an axis of the closure and to a periphery of the closure, the bores being in parallel to the axis and being accessible from a top of the closure; and a break-off head (14B—threaded portion) attached to the top of the closure and breakable therefrom upon application of a preselected torque to the break-off head, the break-off head being free of bores providing axial access the bores by a removal tool, and the bores being positioned so as to be inaccessible by a removal tool until the break-off head is broken from the closure.
- Note: The device as shown in fig. 14 has been turned upside-down, so that the closure is element 14A and the head is element 14B. Note also: The introductory statements of intended use (e.g., "for use with an open-headed medical implant having a pair of spaced and interiorly threaded arms") have been carefully considered but deemed not to impose any structural limitations on the

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claims patentably distinguishable over Dent's device, which is capable of being used as claimed if one desires to do so.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
4. Claims 1-3, 5, 6, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schluder (EP0276153) in view of Grunbichler (5,713,705), and further in view of Johnson (1,300,275). Schluder discloses, at least in the figure and in col. 3, lines 22-26 and lines 57-61; the invention substantially as claimed. Schluder discloses a closure plug usable in an open-headed medical implant having a pair of spaced and interiorly threaded arms, where the plug includes a body with a radially outward surface with a thread thereon (at 5); top and bottom

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surfaces, where the top has two bores (4) sized and shaped to receive a tool and extending generally axially at least partially through the body from top to bottom thereof, where each bore is spaced from a central axis of the body, where the plug includes a break-off head (1) attached to the body and being breakable from the body at a preselected torque; the break-off head being positioned so as to be axially located above the body and being free of pass-through openings; where the body is generally cylindrical in shape, where the body includes a neck (2) positioned between the bores, where the break-off head has a tool-grippable (hexagonal) outer surface, and where the plug includes a tool having a grippable handle and an engagement face including a post extending parallel to an axis of rotation of the tool for each body bore (i.e., a "removal aid" with "two projecting pins" or a "box spanner" with "pins"). However, Schilder does not disclose that the break-off head is axially located above at least a portion of a bore in order to block axial access to by a removal tool, nor does Schilder disclose that a bore is spaced from and positioned between both the central axis and a periphery of the body. Grunbichler teaches, at least in figures 1-11B and in col. 3, lines 10-14 and col. 4, line 66 to col. 5, line 8; a break-off head (3) that is positioned axially above a plug body, so that it axially blocks an entire top surface of the plug body. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Grunbichler, to modify the break-off head, so that it is axially located above at least a portion of a bore (i.e., such that the break-off head axially blocks substantially an entire top surface of a plug body). Such a break-off head would accommodate the application of conventional and readily

available tools for the application of torque to the break-off head (e.g., wrench, ratchet nut, Allen wrench, or screwdriver), where the choices of a tool to be applied and a break-off head would be dependent upon the size and configuration of the plug and the confines of a surgical site as well as the preferences of a surgeon.

Moreover, Johnson teaches, at least in figures 3 and 4 and in lines 70-102; a plug with a body including a bore spaced from and positioned between both the central axis and a periphery of the body, where the bore extends generally axially entirely through the body from top to bottom thereof and opening onto the top surface.. It would have been obvious to one having ordinary skill in the art at the time the invention was made, to modify the plug of Schilder or Schilder in view of Grunbichler, so that the bore is spaced from and positioned between both the central axis and a periphery of the body. Such a bore configuration and position would allow the plug body to receive an entire circumference of a pin of the tool and allow the tool to firmly hold the plug during turning and removal of the plug.

5. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schluder (EP0276153) in view of Grunbichler (5,713,705) and Johnson (1,300,275), and further in view of Wagner (5,334,203). Schluder in view of Grunbichler and Johnson discloses the invention substantially as claimed, but does not disclose three spaced tool receiving bores being spaced 120 deg. from adjacent tool receiving bores. Wagner teaches, at least in figure 1, a closure plug (38) including three spaced tool receiving bores being spaced 120 deg. from

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adjacent tool receiving bores. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Wagner, to modify the device of Schluder in view of Grunbichler and Johnson, so that there are three spaced tool receiving bores being spaced 120 deg. from adjacent tool receiving bores. Such a configuration of bores (and a tool as taught by Wagner) would allow the tool to grip a closure plug and exert more torque for turning the plug and ease its installation or removal.

6. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable Schluder in view of Grunbichler and Johnson, and further in view of Parker et al. (6,053,078). Schluder in view of Grunbichler and Johnson discloses the invention substantially as claimed, but does not disclose four spaced tool receiving bores as claimed. Parker et al. teach, at least in figure 2A and in col. 3, lines 36-46 and col. 4, lines 9-11; a plug (10) with at least four spaced tool receiving tool receiving bores as claimed, which are configured to receive a tool (20). It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Parker et al., to modify the device of Schluder in view of Grunbichler and Johnson, so that there are four spaced tool receiving bores as claimed. Such a configuration of bores would allow the tool to grip the closure plug and transfer more torque for turning the plug and ease its installation or removal.

7. Claims 7, 8, 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schluder in view of Grunbichler and Johnson, and further in view of Reed (6,261,039). Schluder in view of Grunbichler and Johnson discloses

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the invention substantially as claimed, but does not disclose that the body includes an axial extending bore from the bottom to near the top thereof or a threaded axial extending bore passing entirely through the body from a top to a bottom thereof, where the axial bore is located beneath the neck and is accessible from a top of the body when the break-off head breaks away from the body. Reed teaches, in figures 1-3, 11-13, 15, and 16, a closure plug body (10) including a threaded axial extending bore (114) from the bottom to near the top thereof, where the axial bore is located beneath (and through) a neck (30) and is accessible from a top of the body when a break-off head (20) breaks away from the body. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Reed, to include a threaded axial extending bore as claimed in the closure plug of Schluder in view of Grunbichler and Johnson. Such a modification would allow the device of Schluder in view of Grunbichler and Johnson to be used in thread repair, where the axial bore is adapted to receive a desired threaded fastener.

Schluder in view of Grunbichler and Johnson also does not disclose a threaded set screw sized and shaped to be received in the axial bore, where the set screw is sized and shaped to extend outward from the body bottom surface when the screw is fully installed therein. Reed also teaches a set screw (300) to be received in the axial bore. It would also be obvious to one having ordinary skill in the art at the time the invention was made, to include a set screw in the device of Schluder in view of Grunbichler and Johnson, as modified by Reed. Such a screw would allow the thread of the axial bore to remain clean and retain

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its integrity during application of torque to the break-off head. Moreover, it would have been obvious to one having ordinary skill in the art to size the screw, so that it extends outward from the body bottom surface when the screw is fully installed therein, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art.

Response to Amendment

8. Applicant's arguments filed on March 25, 2008 have been fully considered but they are not persuasive. With respect to arguments regarding the rejection based on the Dent reference: The Examiner has deemed the threaded portion 14B of Dent's plug closure to be the break-off head, while portion 14A has been deemed to be the closure; where the Applicant has argued that portion 14B is the closure, and portion 14A is the break-off head. Essentially, figure 14 has been turned upside down. The Examiner has given the claim its broadest reasonable interpretation, and Dent, as described by the Examiner, anticipates the structural limitations as recited in claim 14.

With respect to arguments regarding the rejections based on the Schilder reference: Applicant has argued that Schilder discloses a "bone screw," which has a usage different from the Applicant's closure. Applicant is reminded that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art satisfying the claimed structural limitations. Also, the Examiner agrees with the Applicant that the break-off head of Schilder's device indeed allows access to the

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removal bores. However, given the teachings of Grunbichler for modification of Schilder, the break-off head can be modified to not allow access to the removal bores.

With respect to arguments regarding the Grunbichler reference: Applicant has argued that Grunbichler teaches a bolt from an art that is not the art of the present invention. The Examiner disagrees. Grunbichler, like the present invention, discloses a screw or bolt from an art with fasteners including break-off heads and bodies. Moreover, Applicant is reminded that the determination that a reference is from non-analogous art is twofold. First, we decide if the reference is within the field of the inventor's endeavor. If it is not, we proceed to determine whether the reference is reasonably pertinent to the particular problem with which the inventor was involved. In this case, Grunbichler teaches a fastener from the same art as the present invention, and Grunbichler has teachings regarding the break-off heads pertinent to the particular problem, which the inventor was involved. Moreover, the central bore in Grunbichler is not the claimed bore that is spaced from and positioned between a central axis and a periphery of the body. Also, the claims only require that the head is free of openings for providing access to bores so positioned between a central axis and a periphery of the body. Grunbichler does not disclose such openings in its head.

With respect to arguments regarding the teachings of Johnson: The Examiner agrees that Johnson does not teach a break-off head. However, the Examiner applied Johnson's teaching regarding the positioning of removal bores

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in a threaded body—a teaching used for modifying Schilder in view of Grunbichler.

With respect to arguments regarding the teachings of Wagner: Examiner agrees that Wagner does not teach a break-off head. However, the Examiner applied Wagner's teachings regarding the positioning of and number of removal bores in a fastener body—a teaching used for modifying Schilder in view of Grunbichler and Johnson.

With respect to arguments regarding the teachings of Parker: the Examiner agrees that Parker does not teach a break-off head. However, the Examiner applied Parker's teachings regarding a tool and the positioning of and number of removal bores in a fastener body—teachings used for modifying Schilder in view of Grunbichler and Johnson. Although Parker's devices are applicable to golf shoes, Parker indeed teaches a closure plug nonetheless—a plug usable in golf shoes.

With respect to arguments regarding the teachings of Reed: the Examiner agrees that Reed does not teach removal bores and a break-off head. However, the Examiner only applied Reed's teachings regarding a threaded axial bore in a body and a set screw in the axial bore, where Reed's device is indeed a closure plug.

In summary, the Applicant's arguments regarding Dent, Schilder, Grunbichler, Johnson, Wagner, Parker, and Reed are mainly directed to the intended use of the invention (e.g., "for use with an open-headed medical implant") rather than to structural differences between the invention and the

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reference devices (or combinations thereof). Structurally as claimed, the invention and the reference devices (or combinations thereof) are the same.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Julian W. Woo/
Primary Examiner, Art Unit 3773

July 2, 2008